

# Brennis Consulting Services LLC

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January 27, 2012

Document Processing Desk (PM 31)  
Registration Application  
Office of Pesticide Program (7504P)  
US EPA  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Dear Ms. Noble:

Subject: Micro-Pak  
Enhanced Packaging Stickers (EPA Appl. No. 88401-X)  
Application for Registration

Enclosed is an application for Registration of a sodium metabisulfite product, Enhanced Packaging Stickers. We understand from the pre-application meeting with EPA that this product is considered a new use. This product is being submitted under PRIA action code A500 with a fee of \$11,577. It has been pre-paid.

## New Use

This product is classified as a new use, but it is actually safer than the other sodium metabisulfite products in the marketplace. Most sodium metabisulfite products are in granular form and are for treating grapes in the field. The concentrations of metabisulfite in the other registered products are much higher than this product (18.8%) and the exposure to the chemical is extensive as it is spread on food crops. There are residues on the food crops which are allowable.

The active ingredient in our product is actually mixed directly into a polyethylene material for use in (primarily) shoe boxes to deter mold and mildew. The material is not spread in any way, but is slowly released from this plastic material at extremely low levels. Customers merely place these stickers in the box from individually wrapped stickers and there essentially is no exposure. In addition to that fact, the Toxicity profile is entirely category IV (the lowest category, not requiring any precautionary language).

It seems that there should be no need for an extensive risk assessment or any additional data for review.

## Data Requirements

We have completed both Part A and Part B product chemistry data, including preliminary analysis on the sodium metabisulfite. The product itself is a plastic material with the



active ingredient actually mixed into the plastic during formulation. A preliminary analysis cannot be done on this material because the active cannot be systematically extracted from the plastic, therefore, as allowed in 40 CFR, we have conducted the preliminary analysis on the source material.

We have conducted 5 acute toxicity studies to satisfy product specific data. The eye irritation study is impossible to conduct due to the fact that the active ingredient is bonded to the plastic and there is no real possibility of getting the material in the eye. We are, therefore, requesting a waiver of that study and a request that this route of exposure be classified as toxicity category IV.

All generic data required for sodium metabisulfite are being satisfied by using the "cite all" method. We have included the data submitters list with the data matrix and we are offering whatever compensation may be required to those companies.

### **Toxicity Characteristics and Labeling**

All routes of exposure for this product are toxicity category IV. As indicated in the Agency label manual, we have chosen to not utilize any precautionary text, first aid language or use the term "Caution". We are also requesting that the phrase "Keep Out of Reach of Children" not be required for this product, due to the fact that it will not come in contact with any children as it is placed within the materials that are being treated. After treatment, the product becomes basically inert. This is all identified in the label Manual.

### **The Registered Product**

We discussed the issue of registration in the pre-application meeting and it was agreed that this product will be produced and distributed to various customers who will include the product with packaged leather goods to help minimize mold and mildew.

### **Enclosed is the following:**

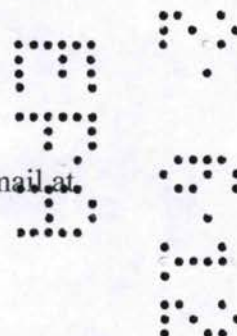
1. Five copies of the label
2. Two copies of the confidential statement of formula (8570-4)
3. One copy of the application form (8570-1)
4. One copy of the certification with respect to data form
5. One copy of the data matrix (both public and private)
6. Three copies of all conducted studies (8 Volumes).
7. One copy of the transmittal document.
8. One copy of the letter of authorization
9. One copy of the payment confirmation email.

If you have any questions, please contact me at 571-275-0556 or at my email at [bob@brennis.com](mailto:bob@brennis.com).

Sincerely,




Robert S. Brennis





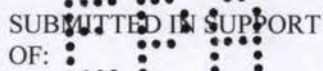
## EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: 

January 27, 2012

STUDY SUBMITTER:

Micro-Pak Ltd.

SUBMITTED IN SUPPORT  
OF: 

Micro-Pak Enhanced Packaging Stickers

EPA REGISTRATION NO.:

88401-X

REGULATORY ACTION:

Application for Pesticide Registration – Old Chemical

STUDIES SUBMITTED:

9 Volumes

STUDY VOLUME 1 of 9:

Chemistry Data for Micro-Pak Enhanced Packaging Stickers (January 27, 2012) by Robert Brennis; 10 pages non-confidential, 11 pages confidential appendix.

*US EPA Guidelines 830.1550, 830.1600, 830.1650, 830.1670, 830.1700, 830.1750, & 830.1800*

MRID Number: 48737101

STUDY VOLUME 2 of 9:

Physical and Chemical Characteristics of Micro-Pak Enhanced Packaging Stickers (January 19, 2012) by Catherine Wo, Ph.D. 13 pages

*US EPA Guidelines 830.6302, 830.6303, 830.6304, 830.6314, 830.7000, & 830.7300*

MRID Number: 48737102

STUDY VOL. 3 of 9

Enforceable Analytical Method for Sodium Metabisulfite (January 27, 2012) by Catherine Wo, Ph.D., 7 pages

MRID Number: 48737103

STUDY VOLUME 4 of 9

Preliminary Analysis of Sodium Metabisulfite (January 19, 2012) by Catherine Wo, Ph.D., 13 pages

*US EPA Guidelines 830.1700*

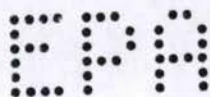
MRID Number: 48737104

STUDY VOLUME 5 of 9:

Acute Oral Toxicity Up and Down Procedures in Rats (January 20, 2012) by Jennifer Durando; 14 pages

*US EPA Guidelines 830.1100 (2002)*

MRID Number: 48737105



EPA TRANSMITTAL DOCUMENT – page 2  
Micro-Pak, Enhanced Packaging Stickers

STUDY VOLUME 6 of 9:

Acute Dermal Toxicity Study in Rats – Limit Test (January 20, 2012) by Jennifer Durando; 14 pages

*US EPA Guidelines 830.1200 (1998)*

MRID Number: 48737106

STUDY VOLUME 7 of 9:

Acute Inhalation Toxicity Study in Rats – Limit Test (January 20, 2012) by Jennifer Durando; 9 pages

*US EPA Guidelines 830.1300 (1998)*

MRID Number: 48737107

STUDY VOLUME 8 of 9:

Primary Skin Irritation Study in Rabbits (January 20, 2012) by Jennifer Durando; 14 pages

*US EPA Guidelines 830.2500 (1998)*

MRID Number: 48737108

STUDY VOLUME 9 of 9:

Dermal Sensitization Study in Guinea Pigs (Buehler Method) (January 20, 2012) by Jennifer Durando; 21 pages

*US EPA Guidelines 830.2600 (2003)*

MRID Number: 48737109

Company Contact:

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